

# Evidence-Based Medicine in the Dialysis Unit

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*A 15 Year Experience with CQI  
in the Dialysis Unit*

# Acknowledgments

These studies were made possible by the current and former staff members of Dialysis Clinic, Inc. of Jackson, Brownsville, Humboldt, and Paris, Tennessee. They are dedicated to the memory of our deceased patients in hope that we learned something from them which helps those who have followed.

# Basic Goals for our Hemodialysis Unit

- 1 Deliver dialysis without inducing symptoms
- 2 Deliver adequate dialysis
- 3 Make sufficient profit to allow for future needs

# Process Indicators: Asymptomatic Dialysis

- What symptoms are induced by dialysis?
- How often do they occur?

Some should never occur, for example, dialyzing with hypotonic dialysate or air embolism

Some are important, but rare, such as febrile reactions

# Process Indicators: Asymptomatic Dialysis

- Hypotension

How is it defined? We decided to count only those decreases in blood pressure that caused the nurse to make an intervention.

- Cramping

- Vomiting

- Leaving the unit above dry weight

# Process Indicators: Asymptomatic Dialysis

- Once we had agreed upon working definitions, it was necessary to begin data collection
- Key Points
  - \* accurate collection
  - \* non-punitive response to the data

# Process Indicators: Asymptomatic Dialysis

<u>Symptom</u>	<u>Control</u>	<u>1</u>	<u>2</u>	<u>3</u>
Hypotension	12.2	10.2	8.8	13.0
Cramping	5.2	4.1	3.0	2.8
Vomiting	1.7	1.0	0.3	1.2
Left Heavy	1.2	1.0	0.3	0.7



## Process Indicators: Adequacy

- Having decided we could deliver dialysis asymptotically about 90% of the time, we decided to turn our attention to adequacy
- We asked ourselves if clinical assessment, combined with routine laboratory studies was as effective as formal urea kinetic modeling

## Process Indicators: Adequacy

- The nurse manager and I predicted which patients would have an inadequate dialysis, defined by a  $Kt/V < 0.8$
- Every patient in the unit had UKM determined using pre- and post- BUN, with the post-dialysis sample drawn 20 minutes after dialysis.
- $Kt/V$  was calculated using a single-pool, variable volume model, (Depner.)

# Process Indicators: Adequacy

		Predicted	
		Adequate	Inadequate
Actual	Adequate	50	9
	Inadequate	17	13

Sensitivity  $13/30=0.43$

Specificity  $50/59=0.85$

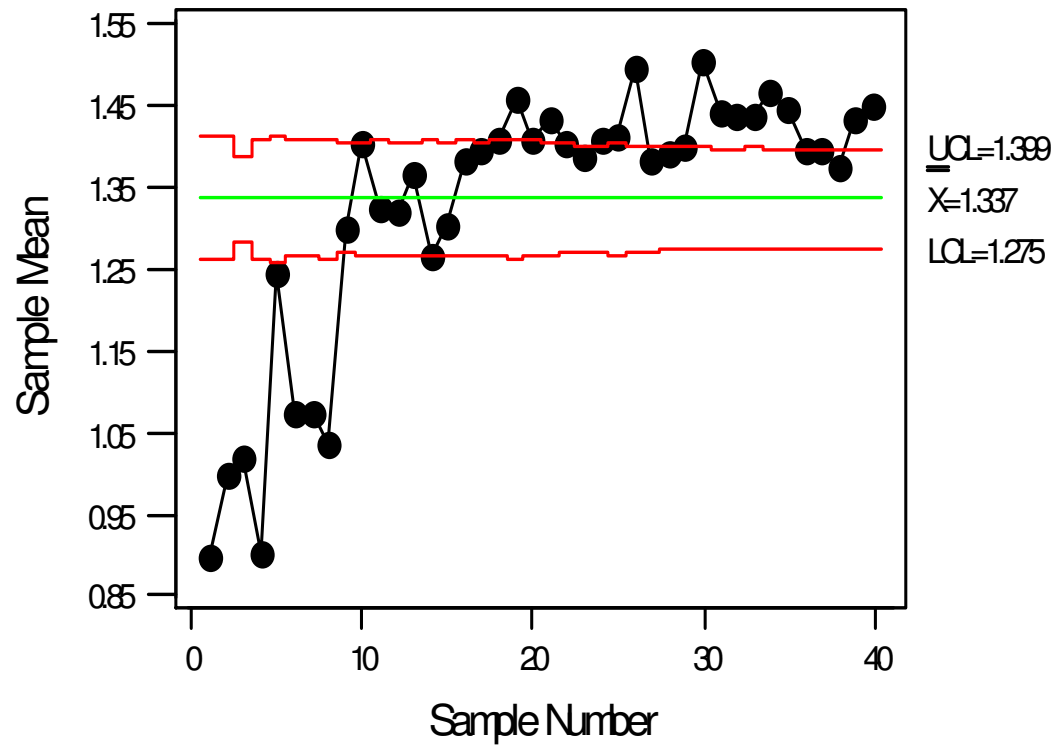
# Process Indicators

- Statistical process control methodology, (Shewart charts) are useful for determining if a process is showing variation within a constant range.
- When a process is operating within its statistically determined confidence limits, it is said to show only common cause variation.

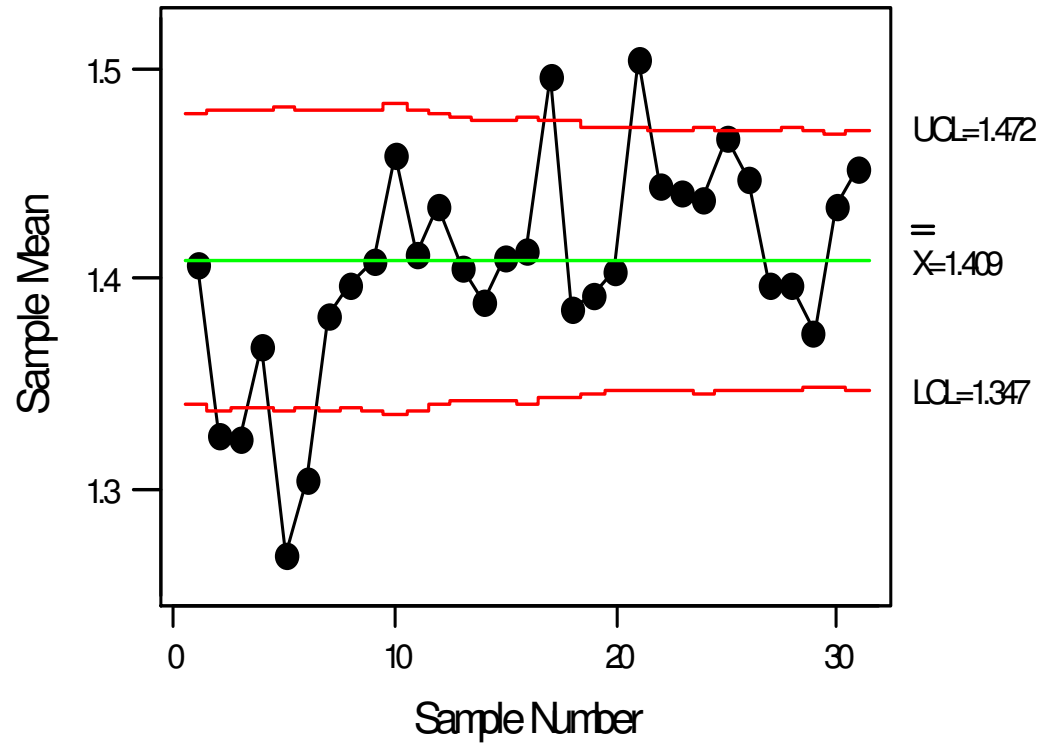
# Process Indicators

- Process control charts may be generated using mean  $Kt/V$ , ( $\bar{X}$  charts) or the percentage of acceptable ( $p$  charts) or unacceptable ( $np$  charts) treatments
- We analyzed all of our UKM measurements from June 1990 through October 1995 to assess the utility of  $Kt/V$  as a process indicator using all three methods.

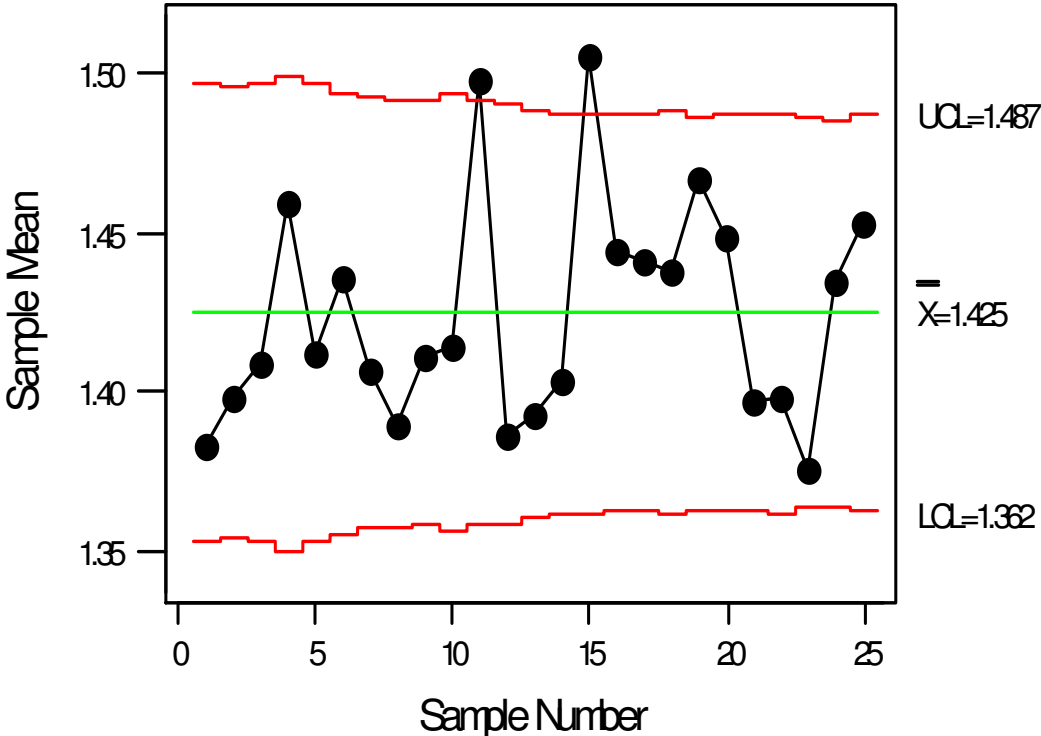
### Mean Delivered Kt/V June 1990-Aug 1995



# Mean Delivered Kt/V Jan 1993-Aug 1995

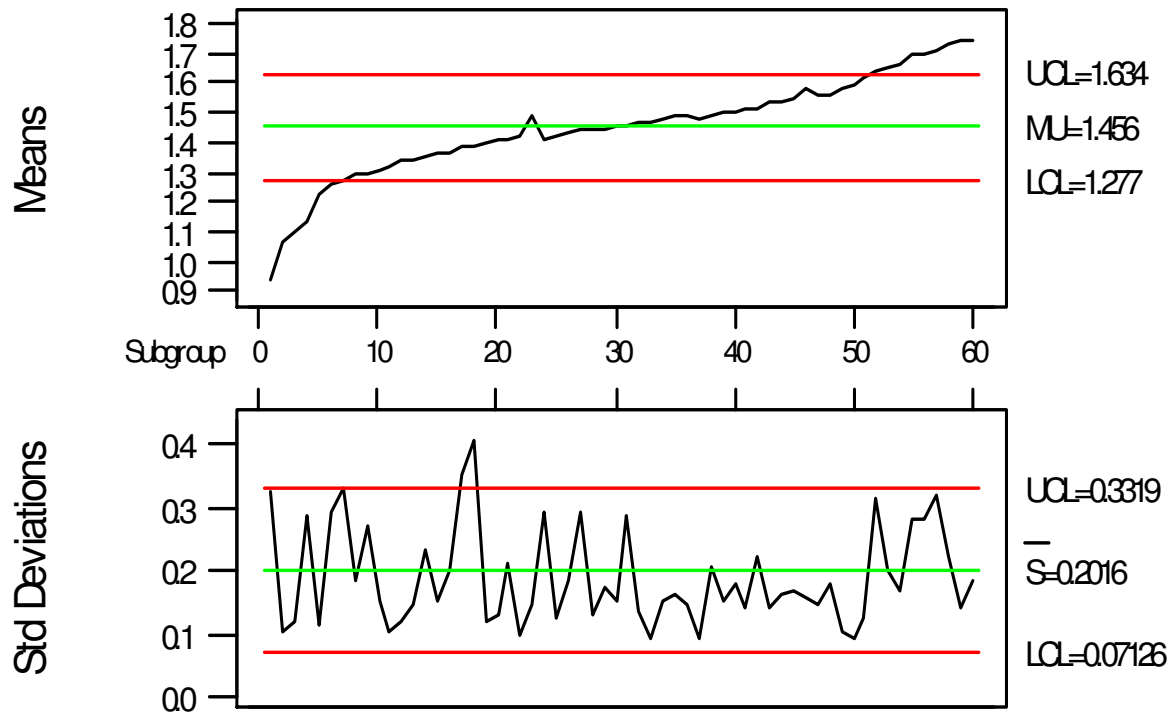


### Mean Delivered Kt/V Jul 1993-Aug 1995





# Individual Variation in Delivered Kt/V



## Process Indicators: Adequacy

- $Kt/V$  measurements have shown the dialysis process to be stable over long periods of time.
- $Kt/V$  measurements do reflect changes in the underlying process
- $Kt/V$  demonstrates a very large common cause variation, the magnitude of which has been stable and unaffected by our CQI processes.

# Indicators

- From this beginning we have evolved a system that now tracks some 25 clinical indicators, 12 technical indicators, and 3 financial indicators

# CQI: Process and Outcomes

- Outcome measures are separate from process measures. Ideally, they should be related to each other.
- Does a change in  $Kt/V$  influence outcome favorably? K/DOQI was produced on the assumption that it does—what is the evidence?

# Some Background Data

- The notion of “improving” outcomes clearly assumes that things are not good enough as they are now.
- The notion that the US ESRD program was delivering inadequate outcomes is based mainly on comparison of the death rates between the US and other first world countries.

# Mortality Comparisons

Table 1: Comparison of the Six National Registries for 1987/1988				
	Acceptance	Prevalence	Transplant	Gross Mortality
	(no./mp/yr 1987)	(no./mp/yr 1987)	(no./mp/yr 1987)	%
Canada	71	186	32	18.9
Germany	76	320	27	10.0
France	56	254	24	7.3
Japan	137	671	<2	8.8
Australia	48	152	25	13.5
<b>USA</b>	<b>151</b>	<b>403</b>	<b>37</b>	<b>23.4</b>
Proceedings From the Morbidity, Mortality and Prescription of Dialysis Symposium				
Dallas, TX, September 15 to 17, 1989. (AJKD 1990;15:375-383)				

# Mortality Comparisons

Table 3: Renal Replacement Therapy Survival Data:						
EDTA Versus US HCFA 1980 to 1984						
Source	No. of Patients	% Survival by Years				
		1	2	3	4	5
EDTA	96,710	88	78	71	64	59
HCFA	110,968	80	66	56	48	42
HCFA*		84	71	62	54	48
Difference		4	7	9	10	11
* Data adjusted to correct for the older age of the US ESRD population						
Proceedings From the Morbidity, Mortality and Prescription of Dialysis Symposium						
Dallas, TX, September 15 to 17, 1989. (AJKD 1990;15:375-383)						

# Possible Explanations

- Older ages accepted
- Diabetes prevalence
- Reimbursement issues
- Transplantation rates
- Co-morbidity
- Adequacy of dialysis
- Nutrition
- Pre-dialysis Care



# Or in the Vernacular

- “My patients are sicker than yours are.”
- “My patients are not compliant with my instructions.”
- “My dialysis company can’t afford to hire enough staff, and won’t pay to keep the good ones.”
- “My referrals always come through the ER and are overtly uremic. If I could start them earlier, they would do better.”

# Our Facility Specific Data (USRDS)

<b>Table 1: Mortality Studies</b>					
	<b>1998</b>	<b>1999</b>	<b>2000</b>	<b>2001</b>	<b>Avg</b>
Patients	195	206	190	182	591
Deaths	31	42	29	18	102
<b>Death Rate</b>	<b>15.9%</b>	<b>20.4%</b>	<b>15.3%</b>	<b>9.9%</b>	<b>17.3%</b>
<b>SMR</b>	<b>0.96</b>	<b>1.31</b>	<b>0.91</b>	<b>0.79</b>	<b>0.85</b>

# Our Facility Specific Data

<b>Table 2: Hospitalization Studies</b>				
	<b>1998</b>	<b>1999</b>	<b>2000</b>	<b>Avg</b>
<b>N</b>	152	158	148	458
<b>Hosp</b>	75	78	73	226
<b>Rate</b>	49.3%	49.4%	49.3%	49.3%
<b>Days/yr</b>	8.6	10.1	4.4	7.7
The SHR ranged from 0.53-0.87 and was statistically significant for three of the four units.				

# Our Facility Specific Data

<b>Table 3: Transplantation Summary</b>				
	<b>1998</b>	<b>1999</b>	<b>2000</b>	<b>Avg</b>
<b>Eligible</b>	102	110	104	326
<b>Actual</b>	10	4	7	21
<b>Rate</b>	<b>9.80%</b>	<b>3.60%</b>	<b>6.70%</b>	<b>6.40%</b>
<b>STR*</b>	<b>0.87</b>	<b>0.75</b>	<b>0.84</b>	<b>0.84</b>
*For each of the three years 1.3 transplants less than expected were performed.				

# Conclusion!

- Implementation of CQI processes that result in meeting or exceeding DOQI recommendations, with the exception of early start and % fistulas does NOT significantly reduce the death rate
- It does significantly reduce the hospitalization rate and the number of days/year spent in the hospital for ESRD patients.

# What about BIAS?

- Center comparisons have shown no consistent pattern of SMR (FMC data)
- There are no consistent correlations between process indicators and mortality (FMC data)
- There are unexplained “center effects” even when adjusting for other possible factors such as co-morbidity. (McClellan, Network data)

# The Single Center Argument

- Bias is probably fairly constant over long periods of time
- This study represents the efforts of two nephrologists, who have agreed about standardized management of common problems
- There are extensive data about the quality of dialysis provided.

# However

- Data to be shown are ours, but the unit level data shown earlier is only 95% our patients, as we do have about 5% managed by other nephrologists, (and that fraction is increasing,) and we have about 7% of our patients in units we do not manage.
- For our units, though, the dialysis management is applicable for ALL patients.



*Are Our Patients Sicker?*

# Outcomes: Mortality

- Low risk
  - age less than 70 with no known medical problems
- Average risk
  - age 70-80 or
  - diabetes or
  - systemic disease without diabetes, age less than 70

# Outcomes: Mortality

## High risk

age greater than 80

age less than 70 with diabetes and another organ system involved, such as heart disease

malignancy

## Medium risk

Age 70-80 or

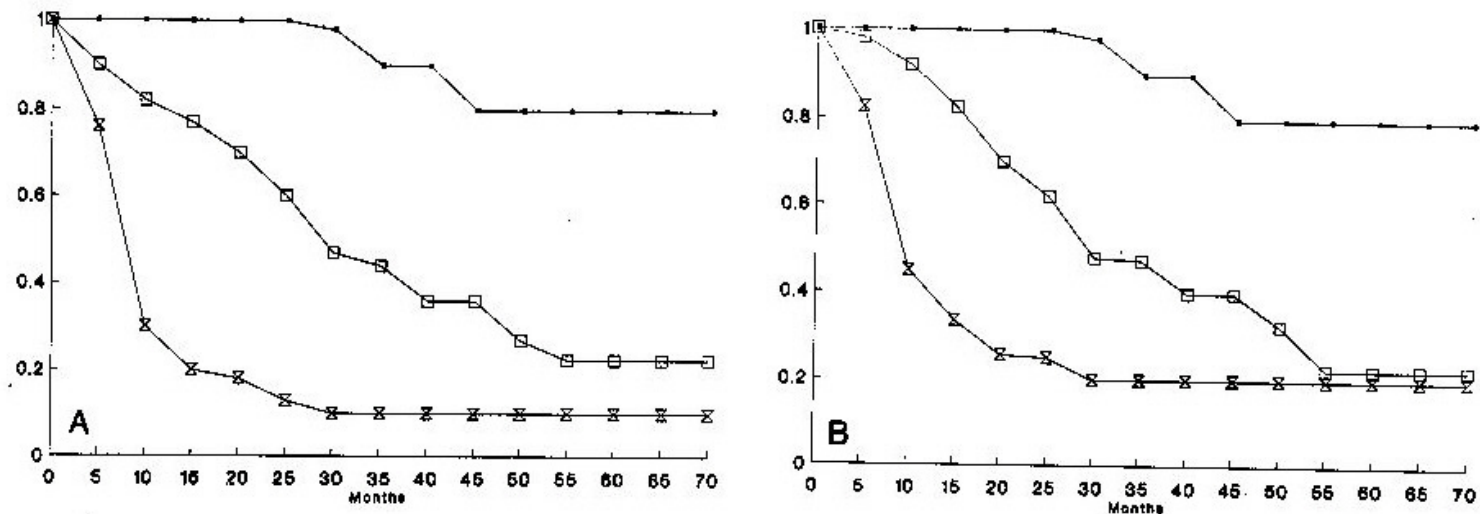
diabetes or

one organ system involvement

# Outcomes: Mortality

## Low Risk

Age less than 70 with no CLINICAL evidence of significant other organ system involvement and no diabetes



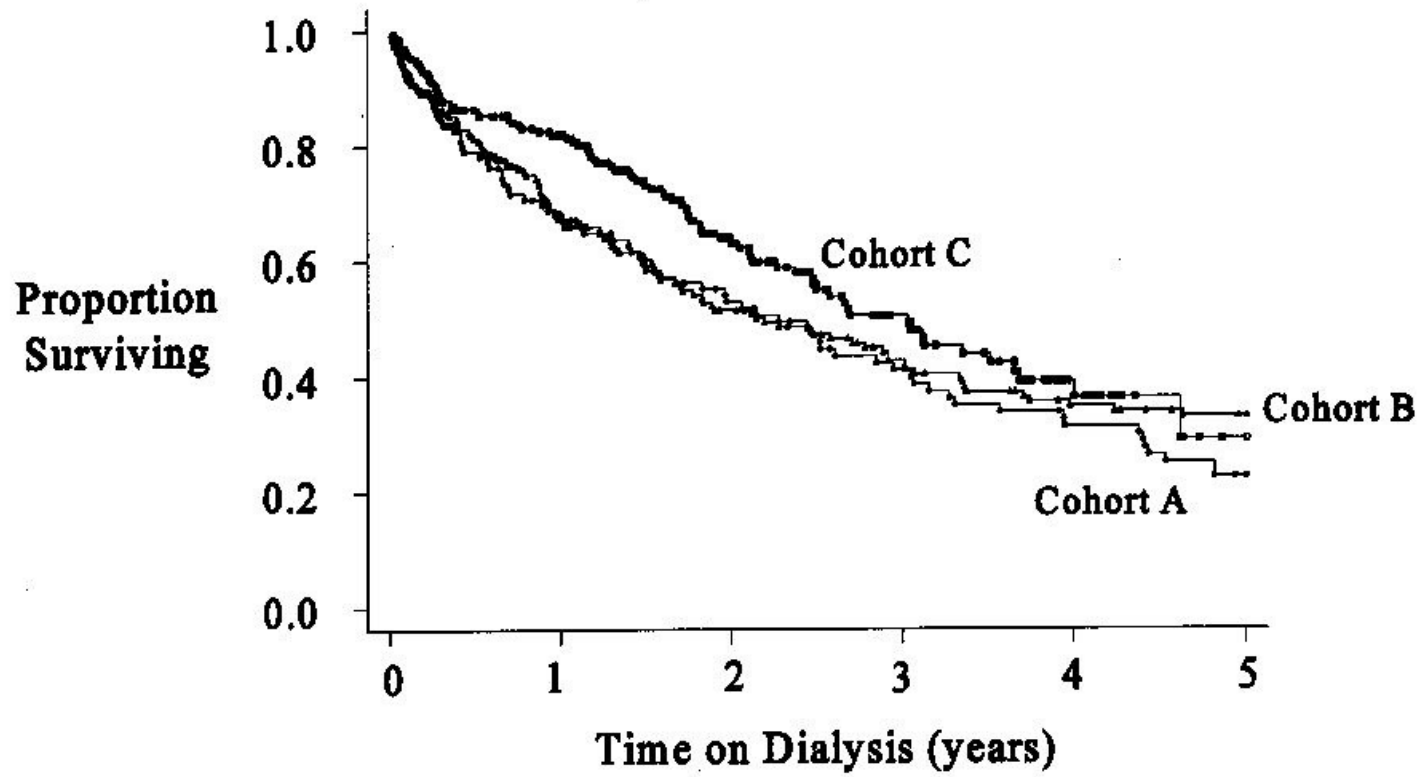
**Fig 1. Kaplan-Meier survival curves for 138 patients classified as low-risk (□—□), average risk (○—○), and high risk (×—×), (A) including the first 90 days, and (B) excluding the first 90 days. The survival curves are significantly different at  $P < 0.0001$  with either set of curves.**

# Extended Study

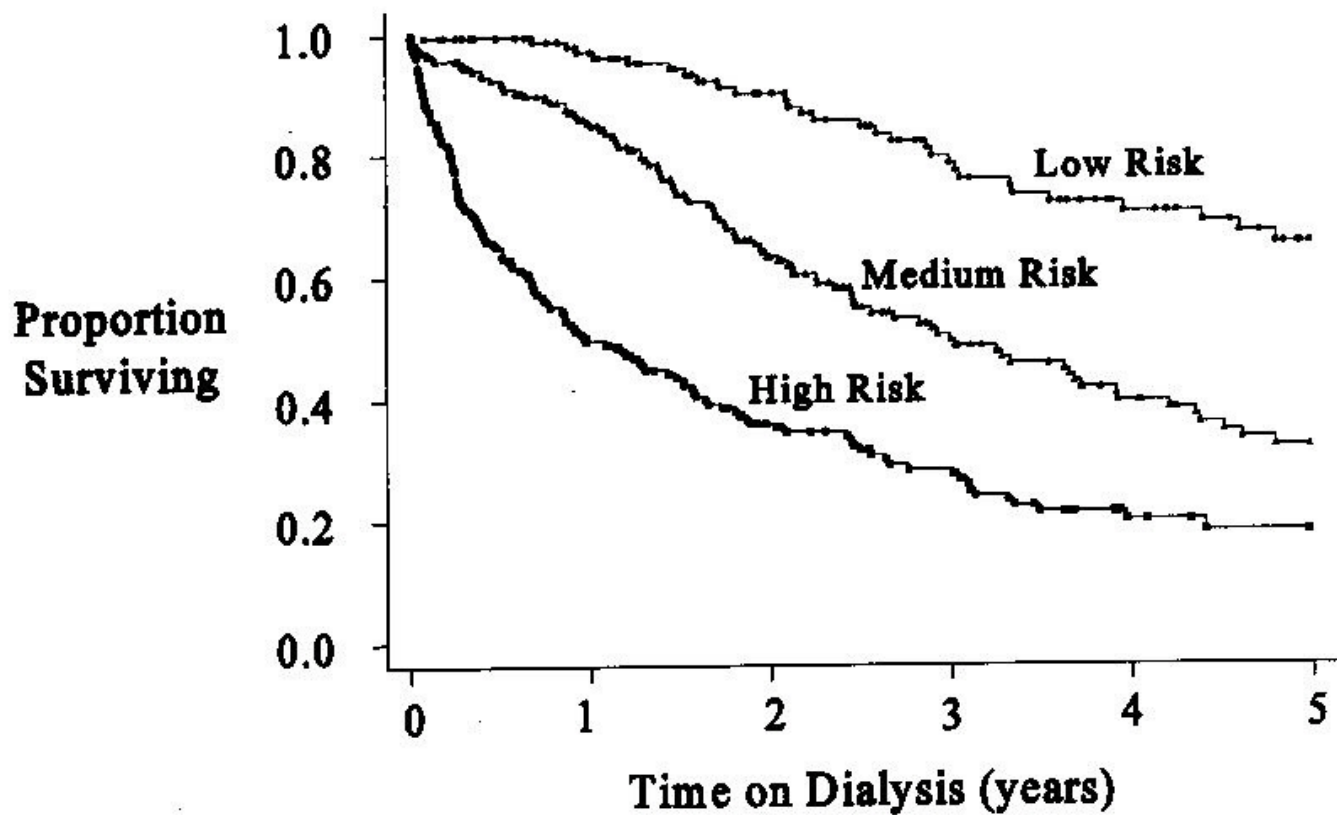
- Prospective cohort study of 553 incident hemodialysis and peritoneal dialysis patients from 1 Jan 1984 through 31 Dec 1996.
- Actuarial survival using life-table methods, and Cox proportional hazard models both adjusted and unadjusted for estimated comorbidity was examined for three cohorts: 1984-1987, (cohort A), 1988-1991, (cohort B), and 1993-1996, (cohort C.)

# Extended Study

<b>Risk Categories for Three Cohorts (%)</b>			
	<b>Cohort A</b>	<b>Cohort B</b>	<b>Cohort C</b>
<b>n</b>	<b>118</b>	<b>178</b>	<b>193</b>
<b>Low</b>	<b>33</b>	<b>25</b>	<b>23</b>
<b>Medium</b>	<b>37</b>	<b>38</b>	<b>38</b>
<b>High</b>	<b>30</b>	<b>39</b>	<b>39</b>







# Extended Study

<b>Table 7: SMR for Hemodialysis Patients 1990-1997</b>				
	<b>Prevalent Patients Only</b>			
<b>Year</b>	<b>Obs</b>	<b>Exp</b>	<b>S. M.</b>	<b>Chi Sq</b>
<b>1990</b>	14	15.87	<b>0.88</b>	0.22
<b>1991</b>	25	19.06	<b>1.31</b>	1.85
<b>1992</b>	15	18.24	<b>0.82</b>	0.58
	54	53.17	<b>1.02</b>	0.01
<b>1993</b>	16	21.11	<b>0.76</b>	1.24
<b>1994</b>	11	22.76	<b>0.48</b>	<b>6.08*</b>
<b>1995</b>	24	27.44	<b>0.87</b>	0.43
<b>1996</b>	26	30.5	<b>0.85</b>	0.66
<b>1997</b>	33	25.93	<b>1.27</b>	1.93
	110	127.74	<b>0.86</b>	2.46
<b>*p,0.05</b>				

# Extended Study

<b>Table 8: SMR for Hemodialysis Patients 1990-1997</b>				
	<b>Incident and Prevalent Patients</b>			
<b>Year</b>	<b>Obs</b>	<b>Exp</b>	<b>S. M.</b>	<b>Chi Sq</b>
<b>1990</b>	16	17.58	<b>0.91</b>	0.14
<b>1991</b>	26	25.32	<b>1.03</b>	0.02
<b>1992</b>	23	26.33	<b>0.87</b>	0.42
	65	69.23	<b>0.94</b>	0.26
<b>1993</b>	17	24.05	<b>0.71</b>	2.07
<b>1994</b>	14	29.64	<b>0.47</b>	<b>8.25*</b>
<b>1995</b>	26	32.68	<b>0.8</b>	1.37
<b>1996</b>	28	34.14	<b>0.82</b>	1.1
<b>1997</b>	39	29.41	<b>1.33</b>	3.13
	124	149.92	<b>0.83</b>	4.48
<b>*p,0.05</b>				

# Conclusions

- Improving the quality of dialysis did, in this historical series, show improved survival in those at greatest risk of death, but not in those at lowest risk.
- The increasing proportion of those at high risk offset any gains in survival as measured by annual mortality rates after a one time gain.

# Another View of Selection Bias

## Hypothesis:

The quality of dialysis is not a significant factor for patients who die in the first 90 days of dialysis, except under extreme conditions

## Issue:

The USRDS data set truncates the first 90 days of dialysis, because a significant number of patients are not covered by Medicare until day 91 of dialysis.

# Another View of Selection Bias

## Corollaries to the hypothesis

- 90 day mortality is a measure of the PHYSICIAN'S skill in selecting patients who are likely to benefit. A high rate of death implies no selectivity.
- Selectivity is an important measure of quality
- A zero early mortality would imply too much selectivity

# Another View of Selection Bias

In other words:

Early mortality in the dialysis population is akin to the “normal” appendix rate for surgeons who perform appendectomies. If the rate is too high, the surgeon is making bad judgments, if it is too low, he/she is missing some patients who need surgery to get the best outcomes.

# Prediction of Early (6 mo.) Death in Canadian Dialysis Patients

- Inception cohort of 822 patients starting dialysis at one of 11 Canadian centers.
- 113 patients (13.7%) died within six months of starting dialysis.
- Numerical scale used to predict likelihood of death.



# Prediction of Early (6 mo.) Death in Canadian Dialysis Patients

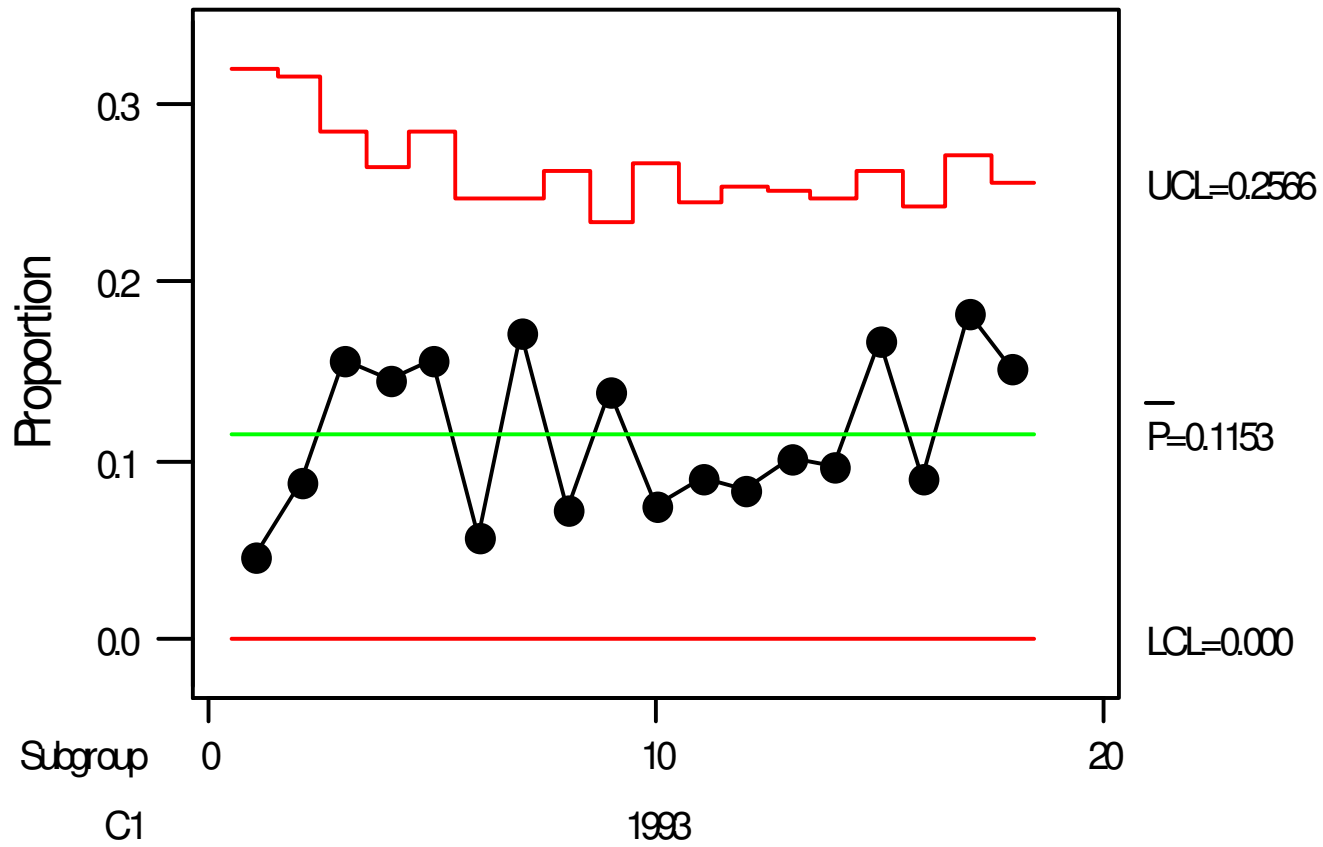
- High adverse scores ( $>9$ ) were found in only 9.7% of patients and only 52% of those died within six months
- No score cutoff combined high true positive and low false positive rates
- Clinicians were very accurate at predicting risk up to 50%--after that they tended to overestimate the risk.

# Early Mortality: The Aberdeen Experience

Table 1: Numbers of Patients and Proportions of Deaths in 90 days

Period	Incident Pts.	Acceptance Rates (per million)	Deaths	%
1971-1981	101	20.1	2	1.9
1981-1991	263	52.6	32	12.1
1991-6/1993	95	76.0	12	12.6

# Early Mortality 1984-2001



# Evidence-Based Medicine and Outcomes in ESRD Patients

# What Happened

- Significant improvements in mortality occurred after introduction of high flux, biocompatible membranes, but only for those patients at highest risk of death.
- Significant reductions in hospitalization rates occurred, but only after EPO and high flux biocompatible membranes became the norm.

# What Happened

- The improvements in dialysis processes cost a great deal of money, although a precise estimate is difficult to establish.
- The reduction in hospitalizations has led to greater outpatient utilization and efficiency, which offset some, but not all, of the cost.

# Conclusions

- Implementing DOQI standards on a national scale will not save money, and will not significantly reduce annual mortality rate over the long term.
- In today's cost-conscious environment, massive investment in "quality" will not be seen as having "value."
- The current fad for "evidence-based" medicine, as manifest by KDOQI, will not significantly change outcomes.

# Why Doesn't EBM Work?

“The rationale for EBM is theoretical argument. Researchers believe in the scientific method. Sound premises and rigorous testing, the principle of falsifiability, and the replication of studies: these are the things that convey legitimacy to researchers. But one person's sound argument may leave another unconvinced.”



# Why Doesn't EBM Work?

- What makes information convincing and, therefore, utilized is a rhetorical question.
- Aristotle argued for three components to rhetoric:
  - Logos—the message, clarity and consistency
  - Pathos—the power to stir emotions
  - Ethos—the credibility, legitimacy and authority of the speaker.

# The Logos

- Much as we may decry it, there is very little “hard” evidence to support our current practice. A minority of the recommendations in KDOQI were considered “A” level, that is, supported by “scientific” evidence.
- Practitioners recognize, and accept the lack of hard evidence, but practice anyway.

# The Pathos

- Medical practitioners want to feel their practices are “high quality.”
- I have made a powerful argument that EBM and CQI are better ways to organize the work of dialysis units.
- A “quality” focus “feels better” when doing your daily work.

# The Ethos

- The “town-gown” split is alive and well in medicine.
- Those who “do” usually don’t collect “the data,” and even when they do, it is not organized in ways familiar to those who “teach.”

# The Ethos

Physicians today feel like cattle being prodded to the slaughter. Everyone wants to control his/her work—either for reasons of intellectual purity or financial gain—but no one wants to step up to the plate and make the call, take the responsibility, and be accountable.

# The Ethos

In fact, the biggest problem facing my large multi-specialty group today is that large numbers of our physicians have decided they don't want to step up to the plate, take call, and be accountable for their decisions. Of course, they do still want to be paid like doctors.

In today's environment, EBM looks like another tool to control physicians—and experience suggests that it, too, is just another Shibboleth.

## Judges 12:5-6 (RSV)

And the Gileadites took the fords of the Jordan against the Ephraimites. And when any of the fugitives of Ephraim said "let me go over," the men of Gilead said to him, "Are you an Ephraimite?" When he said, "No," they said to him, "Then say Shibboleth," and he said "Siboleth," for he could not pronounce it right; then they seized him and slew him at the fords of the Jordan. And there fell at that time forty two thousand of the Ephraimites.



## Judges 12:7 (RSV)

Jephthah judged Israel six years. Then Jephthah died , and was buried at Aijalon in the land of Zebulun.